REMARKS

Applicant courteously requests reconsideration after the Examiner enters this Amendment.

The amended specification addresses clerical matters evident to a person skilled in the art, and avoids new matter.

Applicant presents claims 1-33 for examination. Amended claim 1 finds basis in the original specification throughout, including paragraphs [0019], [0049], and, for instance, the Figs.

A terminal disclaimer is submitted herewith to remove the common law rejection for obviousness-type double patenting.

The claims are definite and the rejection under 35 U.S.C. §112(¶2) based on "at least about" in claim 1 should be reconsidered and withdrawn. The expression "at least" and the expression "about" are terms seen in patent claims. The statute in question nowhere requires any applicant to present a "specific" numerical amount in the claim(s).

Claims 1, 3-6, 16-22 and 24-33 would have been unobvious to a person of ordinary skill in the art over U.S. Patent 6,294,200 to Conte.

Conte '200 describes a tablet with pulsatile release as unequivocally described at column 21, lines 29-31. Conte '200 states there is "an interval of about 60-90 minutes during which a negligible amount of active substance is released."

At column 21, lines 35-39, Conte '200 discloses a fast release of Levodopa in 15 minutes, followed by "an interval of about 2 hours and 2 minutes during which is negligible amount of active substance is released," and thereafter, "fast release of the second quota of Levodopa released in 3 hours for the beginning of the dissolution test". This is consistent with the Office Action at page 4 wherein it is

acknowledged Conte '200 includes an intermediate layer that determines the interval between the release of the active substance contained in the upper layer (1) and the lower layer (3).

Conte '200 describes layer (1) as having 30 mg Carbidopa and 30 mg Levodopa (col. 19, lines 30-47). Conte '200 describes layer (3) as having 27 mg Carbidopa and 100 mg Levodopa.

According to Table VII, column 21, 21% total Levodopa is released in 15 minutes. This means X mg/(30mg + 100mg) = 0.21 or 27 mg Levodopa are released in only 15 minutes.

According to Table VII, column 21, 53.9% of the total Carbidopa is released in 15 minutes. This means Xmg/(30 mg + 27mg) = 0.539 or 30.72 mg Carbidopa are released in 15 minutes.

Claim 1 on the other hand includes an immediate release component that exhibits an *in vitro* dissolution profile comprising at least 10% Levodopa after 15 minutes and at least 60% levdopa release after 1 hour. This is not the dissolution in Conte '200.

In claim 1, the controlled release component has an *in vitro* dissolution profile "comprising from amount 10% and about 60% Levodopa release after 1 hour...". Even at 1 hour, Conte '200 discloses 23.2% Levodopa (cumulative) is released and that amount does not really change during "an interval of about 60-90 minutes during which a negligible amount of active substance is released..." Conte '200, column 21 lines 27-31 (23.2% = 30.16 mg Levodopa released), which teaches away from the controlled released component in claim 1.

In claim 1, the controlled release component has release profile comprising "... about 20 to about 80% Levodopa release after 2 hours..." Conte '200, Table VII,

does not describe any such dissolution profile since at 120 minutes (2 hours) of 23.6% of the total Levodopa is released, *i.e.*, 30.68 mg of Levodopa which is more than is contained in layer (1) in Conte '200. This teaches away from the claimed profile.

In claim 1, the controlled release component has a release profile comprising "... from 30% to 85% Levodopa release after 4 hours..." On the other hand, Conte '200, Table VII, shows 99.9% levodopa is released at 240 minutes (4 hours), which means 129.9 mg are released from the Conte '200 dosage form at 4 hours. Even with the layer (3) in Conte '200, Table VII reports data that show only 0.1 mg levodopa may not have been released at 4 hours, *i.e.*, Conte '200 has almost total dissolution at no later than 4 hours. This is inconsistent with and teaches away from the present invention.

Optimizing the release profile as conjectured in the Office Action at page 5, neither addresses Conte '200 nor the claims, is inconsistent with what Conte '200 discloses in Figs. 1, 2, 3 and 4 and is inconsistent with what Conte '200 discloses in Table VII in view of column 21, lines 27-39.

Conte '200, thus, effectively teaches away from claim 1, and the related claims.

Accordingly, claims 1- 3-6, 16-22 and 24-33 define unobvious inventions over Conte '200.

Claims 2, 7-15 and 23 define unobvious inventions over Conte '200 in view of U.S. Patent No. 6,500,867.

Conte '200 does not teach, describe, suggest, or otherwise lead to Applicant's claimed invention for the reasons discussed above.

The Vikki reference, U.S. Patent No. 6,500,867, simply does not supply the

factual foundation for re-writing Conte '200. In other words, even if, *arguendo* Vikki would have been combined with Conte '200, which is not conceded, the combination would not have suggested, for example, the release profile in Applicant's claims. In fact, as discussed above as to Conte '200, the references teach away from the claimed inventions.

Conclusion

Applicants have endeavored to respond to all matters. Applicants respectfully submit their claims which are in condition to receive a notice of allowance, and such a notice is courteously solicited.

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